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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,888	03/31/2004	Nam T. Chao	DUQ-001 (DEP5289)	9089

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

AMARELD JR, ROBERT W

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,888

Applicant(s)

CHAO ET AL.

Examiner

Robert W. Amareld, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-14 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 & 21, drawn to an implant inserter, classified in class 606, subclass 104.
- II. Claims 15-20, drawn to a method of use for implant inserter, classified in class 606, subclass 104.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to practice another and materially different processes such as being used as a wood router bit, where the tail end, past the handle is engaged into a drill motor and the tabs are used to route a soft wood such as balsa wood.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kevin J. Canning on 1/3/06 a provisional election was made **with traverse** to prosecute the invention of Group, **claims 1-14 &**

21. Affirmation of this election must be made by applicant in replying to this Office action. Claims **15-20 are withdrawn** from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 & 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker (US Pat# 2248054). Becker discloses an engagement mechanism (7) of claws and a shaft (19) movable relative to the first engagement mechanism, with a second engagement mechanism (20) of a blade for selectively engaging the implant screw , which when the two mechanisms are engaged will rigidify the implant from its loose state (Figure 1) to a secured rigidified state (Figure 5) via a distraction between the first portion and second portion, where the first engagement mechanism (20) is pushing the implant, and the second engagement mechanism (7) is pulling the implant. The device

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comprises a body (6) defining an axially extending passage (5) for the spindle shaft (12), where the shaft (12) is within the body/handle (6) and shank (5), which also is a rotatable collar, which when rotated in one direction, relative to the head (13) will cause the shaft to push out the blade portion (20), and when rotated in the other direction will retract the blade. The device includes a transverse screw/pin (14, 24) with a pin projection (15, 25) with a threaded surface for engagement along the insertion slot of the screw/pin (24), which will limit the axial movement of the pin and shaft when fully engaged. The instrument includes alignment protrusions formed on the tip, being a cupped end (26, 27) and the claw (7) protrusions and bias spring (21, column 2, lines 21-29).

Claims 1-4, 7 & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lutz (US Pat#6183472). Lutz discloses a selective engagement mechanism (64,66) for an implant (14), a shaft (46) movable relative to the selective engagement mechanism, where the end surface of the hollow sleeve (42) is a second engagement surface that will which will rigidify the implant when it is retracted and the surface (42) is engaged with the head surface (18) of the implant via a distraction mechanism where surface (42) is pushing and tab portions (66,64) are pulling. The sleeve (46) of the shaft (52) is a rotatable collar surrounding the assembly and is coupled to the shaft by threads (54) such that rotation in one direction will extend the shaft arms (60, 62) and rotation in the other will retract them. The tabs (64, 66) of arms (60, 62) are retractable in a radial direction when the shaft retracts, where tabs will snap out of the recess, and move

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laterally apart, then retract back to the original shape after the screw is released, in an opposite fashion as described in column 3, lines 57-67.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Torrie (US Pat# 5667513). Torrie discloses a device fully capable of being a screw driver for a polyaxial screw where retractable fingers (23-26) are formed on the distal end that are fully capable of selectively engaging the head of a screw, where the end of the fingers are tabs (27) and may engage the shaft portion of a screw. The inner shaft (38) has surface (44), which is fully capable of engaging the shaft portion of a polyaxial screw and fixing it relative to the tabs, and is also capable of actuating the tabs to engage screw recesses. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker (US Pat# 2248054) in view of Lutz (US Pat#6183472). Becker and Lutz are discussed supra, Becker also discloses a rotatable collar (5) attached to the handle (6,

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column 1, lines 50-55). However, Becker does not disclose a plurality of retractable tabs. Lutz teaches a plurality of retractable tabs (60,62,64, 66) in the same field of endeavor or the analogous art of screwdrivers for the purpose of surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of a plurality retractable tabs, as taught by Lutz, to the screw driver as per Becker, in order to better fit into the recesses of a polyaxial screw and to better hold and align a polyaxial screw.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Markworth, US Pat# 6660006 – rod persuader; White, US Pat# 14110088 – screw driver; Keller, US Pat# 6139549 – spinal device ; Allard, US Pat# 5484440 – bone screw and screwdriver; Gilbert, US Pat# 3604487 – screw driver; Stanelle, US Pat# 2593622 – screw holding screw driver; Jackson, US Pat# 5720751 – tools for spinal; Bonati, US Pub# 2004/00668269 – screw extractor; Dunbar, US Pub# 2004/0147937 – rod approximator; Varieur, US Pub# 2005/0149053 – bone anchor device; Puno, US Pub# 2005/0165408 – insertion device..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone

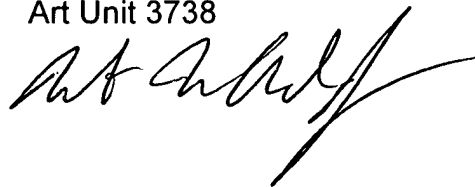
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

Robert W Amareld, Jr.
Examiner
Art Unit 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER

